Remarks

The August 9, 2007 Official Action has been carefully reviewed. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset it is noted that a shortened statutory response period of three (3) months was set forth in the August 9, 2007 Official Action. Therefore, the initial due date for response was November 9, 2007. A petition for a three month extension of the response period is presented with this response, which is being filed within the three month extension period.

At page 4 of the Official Action, the Examiner has objected to the specification for containing the trademark INIFERINE®. Applicants have amended the specification to capitalize the trademark INIFERINE® and provide the generic terminology, thereby overcoming the instant objection.

Claims 1-4, 9, 13, 17-20, 25, and 29 have been rejected for allegedly failing to satisfy the enablement requirement of 35 U.S.C §112, first paragraph.

The Examiner has also rejected claims 1-4, 9, 13, 17-20, 25, and 29 under 35 U.S.C §103(a) as allegedly unpatentable over U.S. Patent 5,824,702 as evidenced by Matsuura et al. (J. Food Sci. (1989) 54:602-605) and Andrews et al. (Appl. Environ. Microb. (1979) 37:559-566).

Claims 1 and 17 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claim 35 of copending U.S. Patent Application No. 10/108,248; claims 1, 18, and 35 of copending U.S. Patent Application 10/885,324; claims 1, 18, and 35 of copending U.S. Patent Application 11/100,905; and claim 17 of copending U.S. Patent Application 11/549,813.

The foregoing objection and rejections constitute all of the grounds set forth in the August 9, 2007 Official Action for refusing the present application.

No new matter has been introduced into this

application by reason of any of the amendments presented herewith.

In view of the present amendment and the reasons set forth in this response, Applicants respectfully submit that the objection to the specification; 35 U.S.C. §112, first paragraph rejection of claims 1-4, 9, 13, 17-20, 25, and 29; the 35 U.S.C. §103(a) rejection of claims 1-4, 9, 13, 17-20, 25, and 29; and the provisional nonstatutory obviousness type double patenting rejections of claims 1 and 17, as set forth in the August 9, 2007 Official Action, cannot be maintained. These grounds of rejection are, therefore, respectfully traversed.

CLAIMS 1-4, 9, 13, 17-20, 25, AND 29, AS AMENDED, SATISFY THE ENABLEMENT REQUIREMENT OF 35 U.S.C. §112, FIRST PARAGRAPH

Claims 1-4, 9, 13, 17-20, 25, and 29 have been rejected for allegedly failing to satisfy the enablement requirement of 35 U.S.C §112, first paragraph. It is the Examiner's position that while the specification is enabling for "reducing the risk of cutaneous tumor development or ultraviolet radiation-induced skin cancer," the specification allegedly does not fully enable the "prevention" of cutaneous tumors or ultraviolet radiation-induced skin cancer.

Applicants respectfully disagree with the Examiner's position. However, in the sole interest of expediting prosecution of the instant application, Applicants have amended claims 1 and 17, from which the other claims depend, to recite "reducing the risk" of cutaneous tumor development in skin cells that have not yet been damaged by ultraviolet radiation or "reducing the risk" of ultraviolet radiation-induced skin cancer, respectively. Accordingly, the instant rejection has been overcome and Applicants respectfully request its withdrawal.

CLAIMS 1-4, 9, 13, 17-20, 25, AND 29 ARE NOT RENDEREDED OBVIOUS BY THE '702 PATENT AS EVIDENCED BY MATSUURA ET AL. AND ANDREWS ET AL.

The Examiner has also rejected claims 1-4, 9, 13, 17-20, 25, and 29 under 35 U.S.C §103(a) as allegedly unpatentable over the '702 patent as evidenced by Matsuura et al. and Andrews et al. The '702 patent allegedly discloses a method of inhibiting the harmful effect of UV radiation exposure by topically applying genistein, a soybean isoflavone. Matsuura et al. allegedly teach that the concentration of genistein is increased during the soaking of soybeans and Andrews et al. disclose that a variety of soybean products are available such as soy flour, soy protein powder, and soy milk powder.

Applicants respectfully disagree with the Examiner's position because the cited prior art fails to teach each and every element of the instantly claimed invention. The instant claims are drawn to methods comprising the administration of at least one composition containing a ***non-denatured*** soy product. At page 7 of the instant specification, a "non-denatured soy product" is defined as a "soy product in which the processing for the derivation of such soy product (e.g., the temperature, extraction media) did not eliminate its ***protease inhibitory activity.***" The references cited by the Examiner fail to teach or suggest a non-denatured soy product which has protease inhibitory activity.

The '702 patent discloses the use of genistein as a preventative agent against UV induced skin damage and cancer. Notably, genistein is the isoflavone 5,7,4'-trihydroxyisoflavone and is not a protein. As such, protocols which denature proteins are routinely used to isolate genistein. Indeed, the '702 patent states that genistein can be purified from soy molasses (column 1, lines 51-52). Soy molasses, however, is denatured. Soy molasses is the aqueous alcohol extract of defatted soybean flakes. More specifically, soy molasses is generated by the alcohol

extraction of defatted soy flakes followed by the removal of the alcohol from the aqueous solvent and then concentrating a distillation residue of the aqueous solvent to the consistency of honey (see, e.g., chapter 5-3-1 of Berk, Z., FAO AGRICULTURAL SERVICES BULLETIN No. 97: TECHNOLOGY OF PRODUCTION OF EDIBLE FLOURS AND PROTEIN PRODUCTS FROM SOYBEANS, Food and Agriculture Organization of the United Nations, Rome, 1992). Additionally, defatted soy generally refers to the soy product after oil extraction, which comprises a step of heat denaturation (see, e.g., chapters 4-2-1 and 4-4-1 of Berk).

The '702 patent also cites Peterson et al. (Biochem. Biophys. Res. Commun. (1991) 179:661-667) as providing an exemplary method for the purification of genistein. Peterson et al. teach at page 663 that genistein was isolated from soy molasses by fractional crystallization according to the method described by Walter (J. Am. Chem. Soc. (1941) 63:3273-3276), which involved cycles of dissolving heat and hexane-extracted soybean flakes in 80% hot ethanol with subsequent cooling to room temperature to form crystals.

In view of the foregoing, it is evident that the '702 patent neither teaches nor suggests the use of a non-denatured soy product. The '702 patent is only concerned with the isoflavone genistein and fails to teach or suggest that genistein has protease inhibitory activity. Isoflavones are isolated from soybeans by organic (denaturing) extraction, as evidenced by the methods cited by the '702 patent. Accordingly, there is no teaching in the '702 patent which would motivate the skilled artisan to use a non-denatured soybean product which has protease inhibitory activity for reducing the risk of cutaneous tumor development or ultraviolet radiation-induced skin cancer, as instantly claimed.

The Examiner also relies on Matsuura et al. as teaching that the concentration of genistein is increased during the soaking of soybeans, which is an early step in the

manufacture of soymilk. However, Matsuura et al. is concerned with the objectionable flavor of soymilk and is, therefore, concerned with soymilk as a consumable liquid. Soymilk for consumption purposes is generally produced by soaking soybeans in water; wet grinding the hydrated soybeans; and then boiling (i.e., denaturing) the resulting slurry in order to improve its nutritional value by heat inactivating protease inhibitors (see, e.g., chapter 8.3 of Berk). Indeed, as noted at page 4, lines 17-30 of the instant specification, soybean protease inhibitors prevent proper digestion and lead to serious digestive problems. Further, Matsuura et al. teach the processing of soy milk at page 603 and describe the boiling of the soybean slurry. Therefore, it is evident that Matsuura et al. merely disclose that the soaking of soybeans results in the hydrolyzation of genistin to genistein. The skilled artisan would look to the '702 patent and the denaturing methods described therein in order to obtain the genistein or the denaturing soymilk production methods described by Matsuura et al. No non-denatured soy product which has protease inhibitory activity is described or suggested by these references.

Lastly, the other reference cited by the Examiner, Andrews et al., is wholly silent as to non-denatured soy products and merely identifies several different forms of soy product.

In stark contrast to the above, the instantly claimed methods encompass non-denatured soy products which have protease inhibitory activity and the specification specifically describes a method of generating soymilk wherein soybeans are soaked in water, grinded, and then, optionally, filtered. The soymilk of the instant invention is not heat-denatured at any stage of processing. Inasmuch as the references cited by the Examiner wholly fail to teach and/or suggest non-denatured soy products, Applicants respectfully submit that the instant rejection of claims 1-4, 9, 13, 17-20, 25, and 29 under 35 U.S.C §103(a) is untenable. Withdrawal of

the rejection is respectfully requested.

DOUBLE PATENTING REJECTIONS

Claims 1 and 17 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claim 35 of copending U.S. Patent Application No. 10/108,248; claims 1, 18, and 35 of copending U.S. Patent Application 10/885,324; claims 1, 18, and 35 of copending U.S. Patent Application 11/100,905; and claim 17 of copending U.S. Patent Application 11/549,813.

Applicants hereby request that the above provisional double patenting rejections be held in abeyance until such time as it is the only rejection remaining in the application, whereupon it should be withdrawn so that either the present application or the above applications may be passed to issue, with the provisional double patenting rejection being converted to a non-provisional double patenting rejection in the other application, as authorized by §804 of the MPEP.

Applicants note, however, that U.S. Patent Application No. 10/108,248 issued as U.S. Patent 7,309,688 on December 18, 2007 after the instant Official Action was mailed. Claim 35 of U.S. Patent Application No. 10/108,248 is now claim 1 of U.S. Patent 7,309,688. Applicants respectfully submit that claims 1 and 17 of the instant application are patentably distinct over claim 1 of the '688 patent. Indeed, claim 1 of the '688 patent recites a "method of inhibiting the progression of a cutaneous tumor comprising topical application of at least one composition containing a non-denatured, Kunitz-type soybean trypsin inhibitor in an amount of from about 0.01-99% by weight." In contrast, claims 1 and 17 of the instant application recite the use of a non-denatured soy product having protease inhibitory activity and do not specifically require a non-denatured, Kunitz-type soybean trypsin inhibitor. Additionally, claim 1 of the '688 patent recites "inhibiting the progression of a cutaneous tumor" whereas the instant claims are drawn to methods of

"reducing the risk of cutaneous tumor development in skin cells that have not yet been damaged by ultraviolet radiation" and "reducing the risk of ultraviolet radiation-induced skin cancer in skin cells that have not been damaged by ultraviolet radiation." In view of the foregoing, Applicants respectfully submit that these are patentably distinct methods.

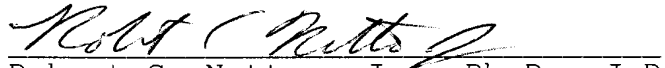
However, in an effort to expedite prosecution of the instant application, Applicants are preparing the necessary declarations and terminal disclaimers to overcome the above nonstatutory double patenting rejections.

CONCLUSION

In view of the amendments presented herewith, and the foregoing remarks, it is respectfully urged that the objection and rejections set forth in the August 9, 2007 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number given below.

Respectfully submitted,
DANN, DORFMAN, HERRELL AND SKILLMAN
A Professional Corporation

By 
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Enclosures: Berk, Z., FAO AGRICULTURAL SERVICES BULLETIN No. 97: TECHNOLOGY OF PRODUCTION OF EDIBLE FLOURS AND PROTEIN PRODUCTS FROM SOYBEANS, Food and Agriculture Organization of the United Nations, Rome, 1992, chapters 4-2-1, 4-4-1, 5-3-1, and 8.3

Peterson et al., Biochem. Biophys. Res. Commun. (1991) 179:661-667

Walter, J. Am. Chem. Soc. (1941) 63:3273-3276